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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,584	07/02/2003	Jacob Waugh	25040-031	5496

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MANATT PHELPS AND PHILLIPS
ROBERT D. BECKER
1001 PAGE MILL ROAD, BUILDING 2
PALO ALTO, CA 94304

EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,584	WAUGH ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) *24-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

.DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-23, 101) in the reply filed on 09/11/2006 is acknowledged.

Claims 24-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/11/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 101 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for linked rapamycin which are linked via attachment to a **polymeric** backbone, does not reasonably provide enablement for any raparmycin containing polymer drug delivery system or one in which a backbone is non-polymeric. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is clear at page 4, lines 3-16 that polymer backbones are contemplated. Rapamycin linked to the back bone is described as the general embodiment at page 9, lines 7-17. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Iyer et al (US Patent 6,726,923).

Iyer et al disclose a drug delivery system comprising a polymer matrix (see col. 3, lines 35 –67; col. 4, lines 1-67. Chitsan of molecular weight up to 5 x 10 is specifically recited at col. 5 lines 1-4. Rapamycin is disclosed as the preferred drug at col. 7, lines 20-34. Also see claims 1-36. The instant claims are clearly anticipated by Iyer et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23, and 101 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 11/517,205 (Us'205). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'205 claims a method of preparing a plurality of linked molecules which specifically bind to mTor and provide a backbone, as well as binding of the plurality of molecules to the backbone (see claims 1 ,22 and 28). The Rapamycin related molecules are set out in claim 2. The number of molecules is set out in claims 3-6, 8-20, 33-34. Specific types of linking moieties and backbones are set out in claims 6-17, 26, 27, 30, 31, 36-52. These include the same polymeric backbones and linking groups used to attach the rapamycin as well as molecules used to bind tissue. As such, those of ordinary skill at the time of invention would have expected similar therapeutic results from the use of the instant polymeric drug delivery system administering a linked rapamycin molecule given the

claims of US'205. As such, the instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of copending US'205.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-23 and 101 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 and 101 of copending Application No. 11/517,207(US'207) . Although the conflicting claims are not identical, they are not patentably distinct from each other because US'207 claims an an implantable prosthesis having a surface structure which has a plurality of linked molecules which specifically bind to mTor and provide a backbone, as well as binding of the plurality of molecules to the backbone (see claim 1). The Rapamycin related molecules are set out in claim 4. The number of molecules is set out in claims 5-7. Specific types of linking moieties and backbones are set out in claims 8-25 These include the same polymeric backbones and linking groups used to attach the rapamycin as well as molecules used to bind tissue. As such, those of ordinary skill at the time of invention would have expected similar therapeutic results from the use of the instant polymeric drug delivery system administering a linked rapamycin molecule given the claims of US'207. As such, the instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of copending US'207.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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